

REMARKS

This is in response to the Office Action mailed November 19, 2003. Claims 1-44 have been canceled. New claims 45-56 are added. Claims 45-56 are pending in the application.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks.

I. Rejection Under 35 U.S.C. § 112

Claims 19, 21-22, 25-27 and 31-33 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement.

Applicants express their appreciation to the Examiner for conducting a telephone interview with Applicants on March 18, 2004. During the interview, Applicants and Examiner discussed the method of treating GVHD using pentostatin in a clinical studies conducted by Goldberg et al. which was partially supported by SuperGen, Inc., assignee of record of the instant application. For the Examiner's convenience and reference, Applicants enclosed another copy of the publication of the clinical studies by Goldberg et al. (2003) "Pentostatin for the Treatment of Chronic Graft-Versus-Host Disease in Children" 25:584-588. This article has been cited in an Information Disclosure Statement mailed to the Examiner on September 5, 2003.

Applicants cancel claims 1-44 and submit new claims 45-55. Independent claim 45 specifies a method for treating GVHD in a transplant recipient by administering to the patient pentostatin in a pharmaceutically effective amount after the transplantation. Support for the claim language in claim 45-56 appear in the Specification, for example, on pages 5-8 under "Summary of The Invention".

The application as originally filed describes in detail how an adenosine deaminase (ADA) inhibitor such as pentostatin can be used to treat or reduce the risk of GVHD. For example, on pages 34-37, detailed description of therapeutic or prophylactic methods and dosing regimens is provided for various types of GVHD, including acute GVHD (page 35, line 14-15) and chronic GVHD (page 36, line 4). In view of Applicant's teaching, one of ordinary skill in the art would be able to understand how to use the claimed invention for treating GVHD without undue

experimentation. Thus, the claimed invention is sufficiently enabling under 35 U.S.C. §112, first paragraph.

However, to aid the Examiner's understanding and appreciation of the invention, Applicants submit herewith the article by Goldberg et al., which describes clinical studies of GVHD in children. The article was published in July 2003, long after the filing date of the instant application, Oct. 12, 2001; and the clinical trials were partially sponsored by the assignee of the application. According to Goldberg et al. the pediatric patients with chronic GVHD were successfully treated with pentostatin (NIPENT, supplied by SuperGen, Inc.). Every patient in the series of clinical studies demonstrated a significant improvement in skin and oral symptoms, and increased incidence of infection secondary to pentostatin was not observed. *See Abstract.* These studies demonstrated the claimed invention can be used to successfully treat GVHD in patients with minimum side effects of pentostatin. As suggested by Goldberg et al., one of the advantages of the pentostatin therapy would be reduction of the dependence on high-dose steroids for the treatment of GVHD.

In view of the adequate teaching of the application, as further supported by clinical evidence, Applicants submit that the claimed invention satisfies the enablement requirement under 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

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CONCLUSION

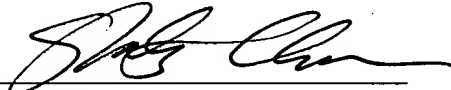
In light of the remarks and arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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